Primary System Organ Class (SOC) Allocation in MedDRA®

MSSO Videocast 01

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Overview

• MedDRA as an ICH standard
• Reason for a primary SOC
• Rules for primary SOC allocation
• Changing a primary SOC allocation
MedDRA as a Standard

• MedDRA developed by an ICH Expert Working Group
• Standardized, international, medically rigorous, maintained terminology
• Facilitates communication of adverse events in regulatory environment
MedDRA as a Standard (cont)

• ICH-endorsed “MedDRA Term Selection: Points to Consider” document

“MedDRA is a standardized terminology. It is considered essential that ad hoc structural changes in MedDRA not occur. The assignment of terms across SOCs is predetermined within the terminology and should not be altered by users.”
A Multi-Axial Terminology

- Multi-axial = the representation of a medical concept in multiple SOCs
  - Allows grouping by different classifications
  - Allows retrieval and presentation via different data sets

- Example: PT *Dyspnoea* linked to:
  - SOC *Respiratory, thoracic and mediastinal disorders* (primary)
  - SOC *Cardiac disorders* (secondary)
Reasons for a Primary SOC

• One SOC is primary; all others secondary
• Primary SOC used in cumulative data outputs (prevents “double counting”)
• Supports consistent data presentation for reporting to regulators
Rules for Primary SOC Allocation

- General rule: prime manifestation site SOC
- Exceptions
  - SOC *Congenital, familial and genetic disorders*
  - SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
    - Exception: Cysts and polyps
  - SOC *Infections and infestations*
Example of Multi-Axiality

**SOC** = Respiratory, thoracic and mediastinal disorders

**HLGT** = Respiratory tract infections

**HLT** = Viral upper respiratory tract infections

**PT** = Swine influenza

**SOC** = Infections and infestations

**HLGT** = Viral infectious disorders

**HLT** = Influenza viral infections
Changing a Primary SOC Allocation

• *Ad hoc* changes undermine MedDRA as a regulatory standard
• Users should submit proposal to change primary SOC assignment through Change Request process
  – MSSO considers justification and established allocation rules
## Example of Primary SOC Change

<table>
<thead>
<tr>
<th>Previous version of MedDRA</th>
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<tbody>
<tr>
<td>SOC <em>Blood and lymphatic system disorders</em></td>
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Summary

• Reviewed concept of primary SOC allocation
• Discussed importance of adhering to allocation rules
• Feedback welcome!
  – Email MSSO Help desk
    • mssohelp@ngc.com